K121722

FLUKE. Biomedical

1/4

Section III -510(k) Summary of Safety and Effectiveness

OCT 11 2012

Submitter:

Fluke Biomedical
6920 Seaway Blvd
Everett WA. 98203
(440) 498-2579 -Phone
(440-349-2307) - Fax
John Nelson –Contact Person

Device Name:

- Trade Name – ESA620 Electrical Safety Analyzer
- Common Name –Analyzer
- Classification Name - Cardiac monitor (including cardiotachometer and rate alarm), per 21 CFR § 870.2300
- Product Codes -DRT

Devices for Which Substantial Equivalence is Claimed:

- MPS450

Device Description:

Principles of Operation

Fluke Biomedical's ESA620 Electrical Safety Analyzer (hereafter referred to as the ESA620) provides a basis for verifying the electrical safety of medical devices. The Product also provides ECG simulation and performance waveforms to verify patient monitors are performing within their operating specifications.

Technological Characteristics

The ESA620 consists of the following components:

1) Printed Circuit Board Assemblies using surface mount components and firmware loaded in embedded processors.
2) Plastic injection molded case parts.
3) Liquid Crystal Display for user interface.
4) Power cord for powering the unit at 120V and 60Hz.

Intended Use of the Device:

The Product is an electronic signal source and measurement device for verifying the electrical safety of medical devices. The Product also provides ECG simulation and performance waveforms to verify patient monitors are performing within their operating specifications.

The Product provides the following function categories:

- ECG Functions
- ECG-Performance Testing

The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment.

The end user is an individual, trained in medical instrumentation technology. This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment.

ESA620 is intended for over the counter use.

Summary of Technological Characteristics:

The ESA620 is substantially equivalent to one other legally marketed and FDA approved device in the United States. The ESA620 functions in a manner similar to and is intended for the similar use as the MPS450 manufactured by Fluke Biomedical.
The ESA620 is similar to MPS450 in that it uses LCD display, and allows user to simulate physiological parameter to verify the operation of patient monitors. The ESA620 differs from MPS450 in that ESA620 works only using AC power cord and has additional options of performing electrical safety analysis.

Features	ESA620	MPS450	Difference
Intended Use	The Product is an electronic signal source and measurement device for verifying the electrical safety of medical devices. The Product also provides ECG simulation and performance waveforms to verify patient monitors are performing within their operating specifications. The Product provides the following function categories: • ECG Functions • ECG-Performance Testing The intended user is a trained	The intended use of MPS450 is to test and verify the basic operation of patient monitoring devices or systems used to monitor various physiological parameters of patient, including ECG, Respiration, Invasive Blood Pressure, and Cardiac Output. The intended user is a trained biomedical equipment technician who is performing periodic preventative maintenance checks on patient monitors in service. Users can be associated with Hospitals, clinics, original	Fewer functions, ESA 620 does not perform Respiration, Invasive Blood Pressure or Cardiac Output

	biomedical equipment technician who performs periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology. This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment. It is intended for over the counter use.	equipment manufacturer or independent service companies that repair and service medical equipment. The end user is technically trained individual, specializing in medical instrumentation technology. The MPS450 is intended to be used in the laboratory environment and is not intended for use on patients, or to test devices while connected to patients. The MPS450 is not intended to be used to calibrate medical equipment and not intended for over the counter use.	3/4
Construction	Plastic Case	Plastic Case	None
Size	12.5" wide x 9.5" deep x 5" high	5.5" wide x 7.5" deep x 1.8" high	Bigger
Weight	9.5 lbs	2lbs	Heavier
Display	5.2'' diagonal screen Monochrome STN transflective	4 line x 20-character super twist LCD display	Larger screen
Function Key	Soft	Soft	None
ECG Leads	10 binding posts; compatible with disposable snaps, 3.2 mm or 4 mm electrodes, and banana plugs (with or without adapter)	10 binding posts; compatible with disposable snaps, 3.2 mm or 4 mm electrodes, and banana plugs	None
Communication s Port	USB	RS232	Change from RS232 to USB data port with advancement in technology
Power	No Battery – AC line powered only	9V alkaline battery with low battery indicator; or battery eliminator; transformer certified	No battery because of higher power requirements

		to CSA	
ECG			
Lead Configuration	12 leads	12 leads	None
Amplitude Accuracy	± 5% of 1mV setting	±2% of setting	Less accurate
Rate Accuracy	± 2% of setting	±1% setting	Less accurate
Normal Sinus Rhythm	30, 60, 120, 180, 240 bpm	30, 40, 45, 60, 80, 90, 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300 bpm	Fewer NSR waves
Sine wave	10, 40, 50, 60, 100 Hz	0.5, 5, 10, 40, 50, 60, 100 Hz	Fewer frequencies
Square wave	0.125, 2.0 Hz	0.125, 2.0 Hz	None
Triangle wave	2.0 Hz	2.0, 2.5 Hz	Fewer frequencies
Pulse wave	30, 60 bpm, 63 ms pulse width	30, 60 bpm, 60 ms pulse width	Wider pulse width
Cable Connector	ECG leads, 10 binding postings	ECG leads, 10 binding postings	None

Substantial Equivalence:

The ESA620 is substantially equivalent to one other legally marketed device in the United States. The ESA620 functions in a manner similar to and is intended for the same use as the MPS450 manufactured by Fluke Biomedical.

The ESA620 is similar to the MPS450 in that it uses LCD display, and allows user to simulate ECG parameters to verify the operation of patient monitors. The ESA620 differs from the MPS450 in that the ESA620 is not battery operated; it performs Electrical Safety Analysis and does not perform respiration, blood pressure or cardiac output.

Non-Clinical Test Data:

Laboratory studies have been conducted with a representative patient monitor to verify and validate the ESA620 will perform within its' published specifications –Document: NPI-05012012-00002

The *ESA620* software has been successfully validated to confirm the performance of the device. Document: NPI-04262012-00002 and NPI-02152012-00002

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the laboratory studies, similar technological/performance characteristics as compared to the predicate device, and successful validation of the *ESA620* software, the performance of the *ESA620* is deemed to be substantially equivalent to the *MPS450*.

000118

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 11 2012

Fluke Biomedical
c/o Mr. John Nelson
Director of Regulatory/Quality Affairs
6045 Cochran Rd.
Solon, OH 44139

Re: K121722
Trade/Device Names: ESA620
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: DRT
Dated: September 18, 2012
Received: September 19, 2012

Dear Mr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FLUKE.
Biomedical

1/1

Indications for Use

510(k) Number (if known): K121722

Device Name: ESA 620 Electrical Safety Analyzer

Indications for Use:

The ESA620 Electrical Safety Analyzer is an electronic signal source and measurement device for verifying the electrical safety of medical devices. The ESA620 also provides ECG simulation and performance waveforms to verify patient monitors are performing within their operating specifications.
The ESA620 provides following function categories:

- ECG Functions
- ECG-Performance Testing

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Cardiovascular Devices

000004

510(k) Number K121722